CLAIMS

1. A pharmaceutical composition comprising 3-(6-(1-(2,2-Difluorobenzo[d][1,3] dioxol-5-yl) cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I and a pharmaceutically acceptable carrier.

2. The pharmaceutical composition of claim 1, which further comprises an additional therapeutic agent.

3. The pharmaceutical composition of claim 2, wherein the additional therapeutic agent is selected from a mucolytic agent, a bronchodialator, an anti-biotic, an anti-infective agent, an anti-inflammatory agent, a CFTR modulator that is not 3-(6-(1-(2,2-Difluorobenzo[d][1,3] dioxol-5-yl) cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid , and a nutritional agent.

4. The pharmaceutical composition of claims 2 or 3, wherein the additional therapeutic agent is N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide.

CLAIMS

1. A pharmaceutical composition comprising:

3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I;

a pharmaceutically acceptable carrier; and

an additional therapeutic agent selected from a mucolytic agent, bronchodialator, an anti-biotic, an anti-infective agent, an anti-inflammatory agent, a cystic fibrosis transmembrane conductance regulator (CFTR) modulator, or a nutritional agent,

wherein Form I is a crystal form having a monoclinic crystal system, a $P2_1/n$ space group, and the following unit cell dimensions:

a = 4.9626 (7) Å $\alpha = 90°$

b = 12.2994 (18) Å $\beta = 93.938$ (9)°

c = 33.075 (4) Å $\gamma = 90°$.

2. A pharmaceutical composition comprising:

3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I;

a pharmaceutically acceptable carrier; and

an additional therapeutic agent selected from a mucolytic agent, bronchodialator, an anti-biotic, an anti-infective agent, an anti-inflammatory agent, a cystic fibrosis transmembrane conductance regulator (CFTR) modulator, or a nutritional agent,

wherein Form I is characterized by one or more peaks 15.2 to 15.6 degrees, 16.1 to 16.5 degrees, and 14.3 to 14.7 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation at 40 kV, 35 mA.

3. The pharmaceutical composition according to claim 1 or 2, wherein the additional therapeutic agent is a CFTR modulator.

4. The pharmaceutical composition according to any of claims 1 to 3, wherein the CFTR modulator is N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide.

5. A pharmaceutical composition according to any of claims 1 to 4 for use in a method of treating cystic fibrosis.

6. Use of a pharmaceutical composition according to any of claims 1 to 4 in the manufacture of a medicament for treating cystic fibrosis.

7. 3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I,

for use in a method of treating cystic fibrosis in a mammal,

wherein an effective amount of Form 1 is to be administered to the mammal; and

wherein an additional therapeutic agent is also to be administered;

wherein Form I is as defined in claim 1 or 2.

8. 3-(6-(1-(2,2-Difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I for use as in claim 7, wherein the additional therapeutic agent is N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide.

9. 3-(6-(1-(2,2-Difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I for use as in claim 7 or claim 8, wherein Form I is to be administered concurrently with, prior to, or subsequent to the additional therapeutic agent.

10. N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide for use in a method of treating cystic fibrosis in a mammal,

wherein an effective amount of N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide is to be administered to the mammal; and

wherein an additional therapeutic agent which is 3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl) cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I is also to be administered;

wherein Form I is as defined in claim 1 or 2.

11. N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide for use as in claim 10, wherein Form I is to be administered concurrently with, prior to, or

subsequent to 3-(6-(1-(2,2-Difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I.

12. Use of 3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl) cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I in the manufacture of a medicament for use in a method of treating cystic fibrosis in a mammal,

wherein the medicament is prepared for administration to the mammal in an effective amount; and

wherein the medicament is prepared for administration with an additional therapeutic agent;

wherein Form I is as defined in claim 1 or 2.

13. Use according to claim 12, wherein the additional therapeutic agent is N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide.

14. Use according to claim 12 or claim 13, wherein the medicament is prepared for administration concurrently with, prior to, or subsequent to the additional therapeutic agent.

15. Use of N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide in the manufacture of a medicament for use in a method of treating cystic fibrosis in a mammal,

wherein the medicament is prepared for administration in an effective amount; and

wherein the medicament is prepared for administration with an additional therapeutic agent which is 3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid characterized as Form I;

wherein Form I is as defined in claim 1 or 2.